

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01608

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3063446 A (M.R. LEVITT), 13 November 1962 (13.11.62), column 1, line 36 - line 42	1
A	--	2-10
X	DE 454875 C (HERMANN EICHLER), 18 January 1928 (18.01.28), column 1, line 36 - line 38	1
A	--	2-10
X	CH 564344 A (MARGARETA ESCHLE), 31 July 1975 (31.07.75)	1
A	--	2-10

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"B" document member of the same patent family

Date of the actual completion of the international search

17 December 1999

Date of mailing of the international search report

22-01-2000

Name and mailing address of the ISA:

Swedish Patent Office

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01608

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4632103 A (FABRICANT ET AL), 30 December 1986 (30.12.86), figure 3, abstract	1
A		2-10
X	JP 10234759 A (SUGAWARA M) 1998-09-08 (abstract) World Patents Index (online). London, U.K.: Derwent Publications, Ltd. (retrieved on 1999-12-16) Retrieved from: EPO WPI Database. DW9846, Accession No. 98-535384; JP 10234759 (SUGAWARA MASATOSHI) 1998-12-31 (abstract), (online) (retrieved on 1999-12-16). Retrieved from EPO PAJ Database.	1
A		2-10

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.
PCT/SE 99/01608

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3063446 A	13/11/62	NONE	
DE 454875 C	18/01/28	NONE	
CH 564344 A	31/07/75	NONE	
US 4632103 A	30/12/86	NONE	

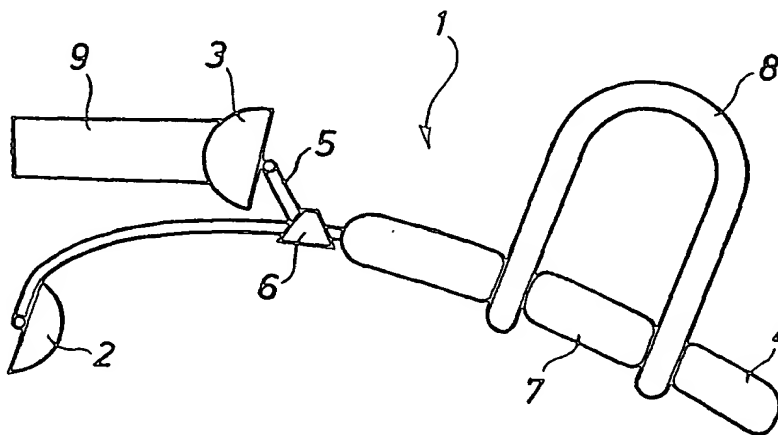
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 5/01	A1	(11) International Publication Number: WO 00/15163 (43) International Publication Date: 23 March 2000 (23.03.00)
<p>(21) International Application Number: PCT/SE99/01608</p> <p>(22) International Filing Date: 15 September 1999 (15.09.99)</p> <p>(30) Priority Data: 9803110-7 15 September 1998 (15.09.98) SE</p> <p>(71) Applicant (for all designated States except US): CAMP SCANDINAVIA AB [SE/SE]; Karbingatan 38, S-254 67 Helsingborg (SE).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): SMITS, Jan [NL/NL]; Holterbergweide 26, NL-5709 MP Helmond (NL).</p> <p>(74) Agents: ÅKERMAN, Mårten, L. et al.; Albihs Patentbyrå Malmö AB, P.O. Box 4289, S-203 14 Malmö (SE).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: HALLUX VALGUS BRACE

(57) Abstract

The invention relates to a hallux valgus brace, i.e. a brace designed for treatment of non-rigid hallux valgus. The brace comprises a three point lever means for correcting the position of the big toe. According to the invention the complete brace (1) is designed to be located distally of the metatarsal joint. Preferably, the brace comprises a proximal pad (2) pressing on the first phalanx of the big toe, a distal pad (3) pressing on the distal end of the first phalanx of the big toe, and a lever arm (4) pressing on the ball of the foot. The brace can be used during walking and other activities.



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AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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HALLUX VALGUS BRACE

Field of the invention

The present invention relates to a hallux valgus brace, i.e. a brace designed
5 for treatment of non-rigid hallux valgus. The complete brace is positioned in front
of the metatarsal joint and can be used during walking and other activities.

State of the art

Hallux valgus is a painful malposition of the big toe, where the big toe turns
10 towards the other toes and a bunion is formed on the protruding joint, i.e. the first
metatarsal joint. This deformity has been treated in the past mainly by means of
night splints or braces. The brace is mainly used during sleeping or resting. The
brace uses three pressure points, two of which are located at the metatarsus. Thus,
the prior art brace requires support proximal of the metatarsal joint. The brace
15 bridges the metatarsal joint resulting in that the brace is not suitable for walking
because the bending of the joint together with the brace is not comfortable or even
impossible.

The present invention solves this problem by positioning the complete brace
distally of the metatarsal joint. Thus, all components of the brace are located
20 distally of the metatarsal joint and the brace is not affected by the bending of the
joint during walking and other activities. In this way, the brace of the invention
may be used for conservative dynamic treatment of non-rigid hallux valgus. In
other words, the patient may wear the brace practically at all times resulting in an
efficient treatment.

25

Summary of the invention

Thus, the present invention provides a hallux valgus brace comprising a
three point lever means for correcting the position of the big toe.

According to the invention the complete brace is designed to be located
30 distally of the metatarsal joint. Preferably, the brace comprises a proximal pad
pressing on the medial side on the first phalanx of the big toe, a distal pad pressing
on the distal end of the first phalanx, and a lever arm pressing on the ball of the
foot.

The invention is defined in claim 1 while preferred embodiments are set
35 forth in the dependent claims.

Brief description of the drawings

The invention will be described in detail below with reference to the accom-
panying drawings in which:

figure 1 is a top view of the brace on the foot of a patient;
figure 2 is a detail view of one component of the brace carrying the distal pad;

figure 3 is a detail view of the main part of the brace; and
5 figure 4 is a top view of the complete brace according to the invention.

Detailed description of preferred embodiments

The hallux valgus brace according to the invention is now described with reference to the drawings. In figure 1, the brace is shown as worn by a patient on a
10 foot. The skeletal bones of the foot are shown for reference. In figure 4, the complete brace 1 is shown by itself. The brace is located in the space which exists under the normally slightly bent toes. At the medial side the brace carries a proximal pad 2 pressing on the first phalanx of the big toe. A distal pad 3 is carried by an adjustable arm 5 and presses on the distal end of the big toe, preferably on
15 the distal end of the first phalanx.

The pads 2 and 3 are connected to the frame of the brace by means of hinges, so that the pads can turn and adapt themselves to the curvature of the contact area between the pads and the toe. Thus, the pads 2 and 3 are self-adjusting for better fit and comfort.

20 The lateral part of the brace comprises a lever arm 4 pressing backwards and acting as a counterforce on the ball of the foot. The lever arm 4 also carries a strap 8, best shown in figures 3 and 4. Another toe is inserted through the strap 8 serving to prevent the lever arm 4 from sliding down. This is preferably the third toe since this toe is a little longer and stronger but also e.g. the fourth toe could be used.

25 The adjustable arm 5 is connected to the main part of the brace by means of a sleeve 6. The sleeve 6 may be slid to a correct position in order to accommodate various sizes of big toes. When the sleeve 6 is positioned correctly it may be fixed with glue.

30 The brace is manufactured from stainless steel spring-wire, thickness e.g. 1,75 mm. The pads 2 and 3 are cup shaped pads, made of steel sheet, thickness e.g. 0,6 mm or injection moulded plastic. The adjustable sleeve 6 is also preferably made of stainless steel.

For best comfort the lever arm 4 may carry a silicone tube 7. The strap 8 is suitably made of rubber or plastic, but may also be made of leather, cotton or a
35 hook and loop connection (Velcro® fastening).

The distal pad 3 may carry another strap or fastening means 9 to be located around the big toe and preventing the pad from sliding off. This strap 9 suitably comprises a hook and loop connection for easy fastening and adjustment.

The brace according to the invention can be used in a dynamic way. Since

all correcting and stiff parts are located distally of the metatarsal joint the brace does not interfere with normal walking. The brace has a lever means with a clear three point working principle. A force A on the medial side moves the first phalanx laterally while a force B on the lateral side moves the distal end of the first phalanx
5 and the toe medially. The reaction force C is applied against the soft tissue of the ball of the foot.

For the brace of the invention to be efficient the first metatarsal joint needs to be flexible enough to be repositioned and flexed in a horizontal plane. The patient should wear a shoe or slipper providing sufficient room for the medial
10 movement of the toe.

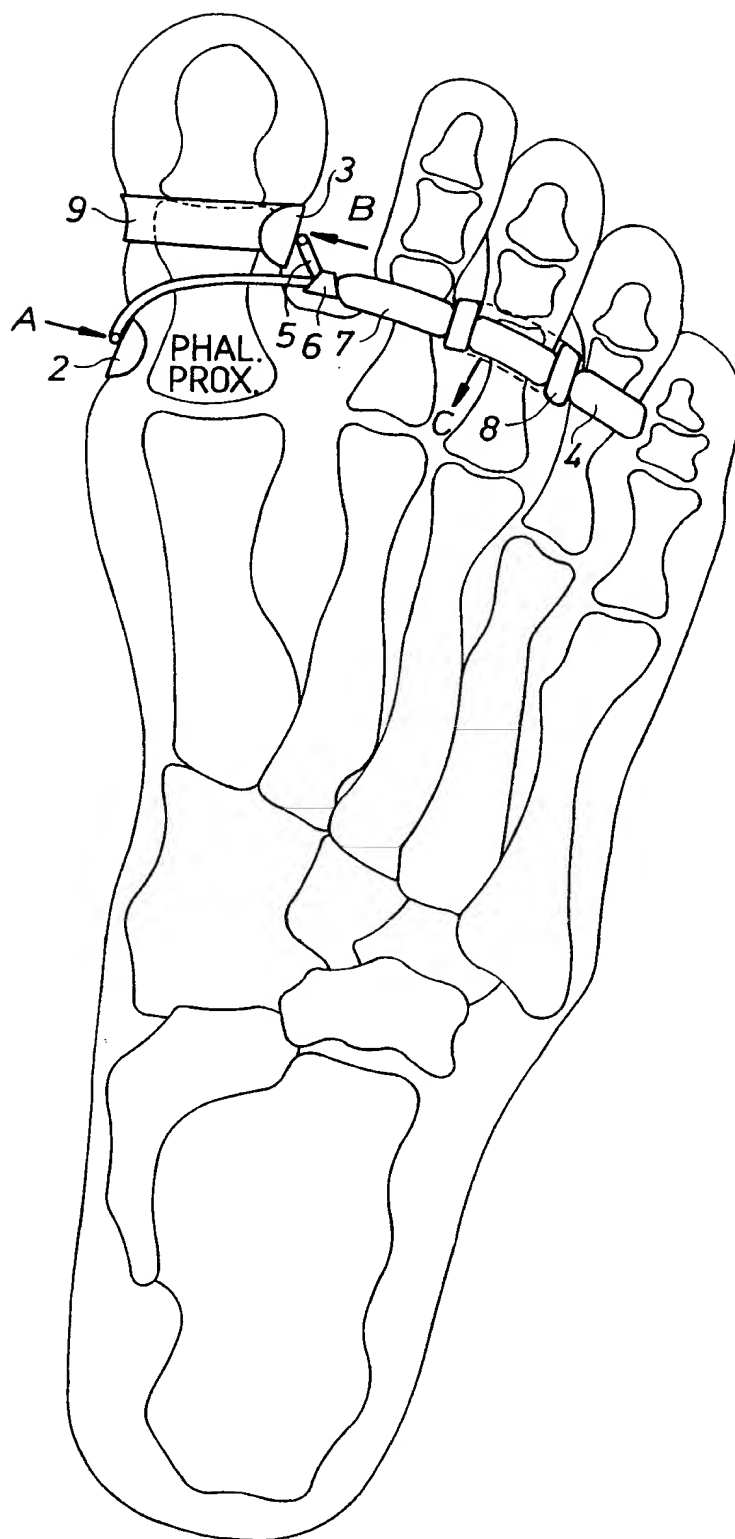
The brace according to the invention is intended to be delivered as an "of the shelf" item and requires adjustments before it can be worn by a patient. Thus, the wire parts of the brace are bent for a proper fit. The sleeve 6 is positioned correctly and preferably glued to secure it to the wire. It is suitable that this work is
15 performed by an orthotist/bandagist or possibly a podiatrist, even if patients eventually may learn to fit the braces themselves.

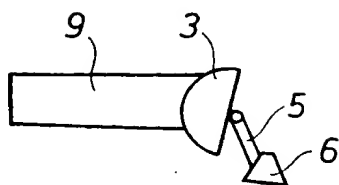
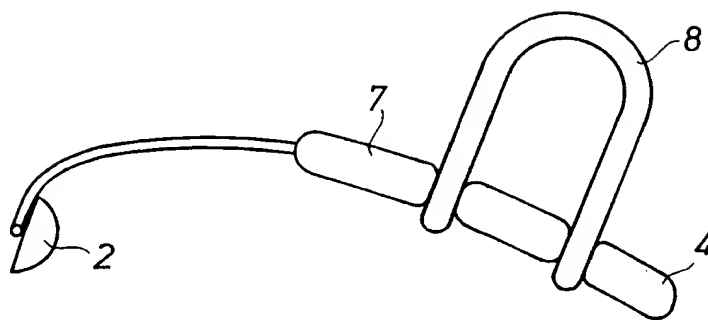
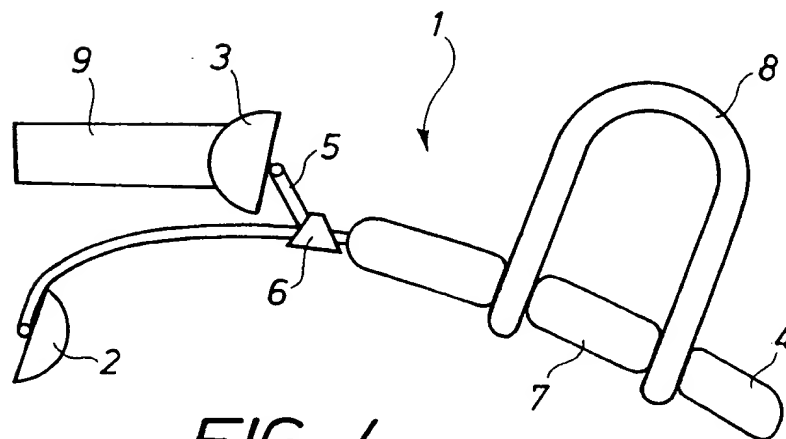
Thus, the present invention provides several advantages over the prior art. The brace allows for a dynamic treatment since the brace may be used at all times during walking, resting etc. and in normal shoes. The brace is adaptable for various
20 foot sizes by means of some simple adjustments only. The brace is very light-weight and very comfortable.

A person skilled in the art will appreciate that the brace of the invention may be modified without departing from the scope of the invention. Thus, the embodiment shown is just given as an example of shapes and materials that may be used.
25 The scope of the invention is only limited by the claims below.

CLAIMS

1. A hallux valgus brace comprising a three point lever means for correcting the position of the big toe, **characterised** in that the brace (1) is
5 designed to be located distally of the metatarsal joint.
2. A brace according to claim 1, **characterised** in that the brace (1) comprises a proximal pad (2) pressing (A) on the first phalanx of the big toe, a distal pad (3) pressing (B) on the distal end of the big toe, and a lever arm (4) pressing (C) on the ball of the foot.
- 10 3. A brace according to claim 2, **characterised** in that the distal pad (3) is adapted to press (B) on the distal end of the first phalanx of the big toe.
4. A brace according to claim 2 or 3, **characterised** in that the distal pad (3) is disposed on an adjustable arm (5).
5. A brace according to claim 4, **characterised** in that the adjustable arm
15 (5) is secured to a sleeve (6) which is slidable and may be fixed with glue.
6. A brace according to any one of the preceding claims, **characterised** in that the brace is manufactured from steel wire and steel pads.
7. A brace according to any one of claims 2-6, **characterised** in that the lever arm (4) is provided with a silicone tube (7).
- 20 8. A brace according to any one of the preceding claims, **characterised** in that a strap (8) is provided for fitting around the third toe.
9. A brace according to claim 7, **characterised** in that the strap (8) is made of rubber or plastic or a hook and loop connection.
10. A brace according to any one of the preceding claims, **characterised** in
25 that the distal pad (3) carries a strap (9) to be located around the big toe.

**FIG. 1**

*FIG. 2**FIG. 3**FIG. 4*

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WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3063446 A (M.R. LEVITT), 13 November 1962 (13.11.62), column 1, line 36 - line 42	1
A	--	2-10
X	DE 454875 C (HERMANN EICHLER), 18 January 1928 (18.01.28), column 1, line 36 - line 38	1
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

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22 -01- 2000

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01608

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4632103 A (FABRICANT ET AL), 30 December 1986 (30.12.86), figure 3, abstract	1
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X	JP 10234759 A (SUGAWARA M) 1998-09-08 (abstract) World Patents Index (online). London, U.K.: Derwent Publications, Ltd. (retrieved on 1999-12-16) Retrieved from: EPO WPI Database. DW9846, Accession No. 98-535384; JP 10234759 (SUGAWARA MASATOSHI) 1998-12-31 (abstract), (online) (retrieved on 1999-12-16). Retrieved from EPO PAJ Database.	1
A	-- -----	2-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.

PCT/SE 99/01608

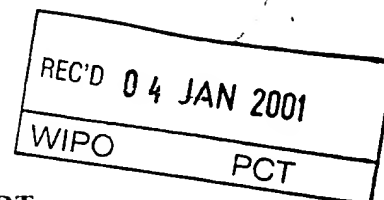
Patent document cited in search report			Publication date	Patent family member(s)	Publication date
US	3063446	A	13/11/62	NONE	
DE	454875	C	18/01/28	NONE	
CH	564344	A	31/07/75	NONE	
US	4632103	A	30/12/86	NONE	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P10797/MÅ	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE99/01608	International filing date (day month year) 15.09.1999	Priority date (day month year) 15.09.1998
International Patent Classification (IPC) or national classification and IPC7 A61F 5/01		
Applicant Camp Scandinavia AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 27.03.2000	Date of completion of this report 19.12.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Ingrid Falk/js Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01608

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed
- ☒ the description:
pages 1, 3 . as originally filed
pages 2 . filed with the demand
pages _____ . filed with the letter of _____
- ☒ the claims:
pages _____ . as originally filed
pages _____ . as amended (together with any statement) under article 19
pages 4 . filed with the demand
pages _____ . filed with the letter of _____
- ☒ the drawings:
pages 1 - 2 . as originally filed
pages _____ . filed with the demand
pages _____ . filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____ . as originally filed
pages _____ . filed with the demand
pages _____ . filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01608

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-10</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-10</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-10</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The invention relates to a hallux vulgus brace comprising a three point lever means that is designed to be located distally of the metatarsal joint.

Amended claims were filed on 03.27.2000. Claim 1 has been made clear concerning the location of the points in the three point lever means. Hence, the first point is located on the medial side of the first phalanx of the big toe, the second point on the lateral side of the distal end of the big toe and the third point on the ball of the foot.

In the International Search Report the following documents were cited:

(D1) US 3063446 A
 (D2) DE 454875 C
 (D3) CH 564344 A
 (D4) US 4632103 A
 (D5) JP 10234759 A

The documents show different means for correcting the position of the big toe. None of the documents reveals a three point lever means according to the new claims.

Thus, the invention is novel. The invention is also unobvious to a person skilled in the art. Accordingly, it involves an inventive step. The industrial applicability of the invention is obvious.

27-03-2000

figure 1 is a bottom view of the brace on the foot of a patient;
figure 2 is a detail view of one component of the brace carrying the distal
pad;

figure 3 is a detail view of the main part of the brace; and
5 figure 4 is a bottom view of the complete brace according to the invention.

Detailed description of preferred embodiments

The hallux valgus brace according to the invention is now described with
reference to the drawings. In figure 1, the brace is shown as worn by a patient on a
10 foot. The skeletal bones of the foot are shown for reference. In figure 4, the
complete brace 1 is shown by itself. The brace is located in the space which exists
under the normally slightly bent toes. At the medial side the brace carries a
proximal pad 2 pressing on the first phalanx of the big toe. A distal pad 3 is carried
by an adjustable arm 5 and presses on the distal end of the big toe, preferably on
15 the distal end of the first phalanx.

The pads 2 and 3 are connected to the frame of the brace by means of
hinges, so that the pads can turn and adapt themselves to the curvature of the
contact area between the pads and the toe. Thus, the pads 2 and 3 are self-adjusting
for better fit and comfort.

20 The lateral part of the brace comprises a lever arm 4 pressing backwards and
acting as a counterforce on the ball of the foot. The lever arm 4 also carries a strap
8, best shown in figures 3 and 4. Another toe is inserted through the strap 8 serving
to prevent the lever arm 4 from sliding down. This is preferably the third toe since
this toe is a little longer and stronger but also e.g. the fourth toe could be used.

25 The adjustable arm 5 is connected to the main part of the brace by means of
a sleeve 6. The sleeve 6 may be slid to a correct position in order to accommodate
various sizes of big toes. When the sleeve 6 is positioned correctly it may be fixed
with glue.

30 The brace is manufactured from stainless steel spring-wire, thickness e.g.
1,75 mm. The pads 2 and 3 are cup shaped pads, made of steel sheet, thickness e.g.
0,6 mm or injection moulded plastic. The adjustable sleeve 6 is also preferably
made of stainless steel.

For best comfort the lever arm 4 may carry a silicone tube 7. The strap 8 is
suitably made of rubber or plastic, but may also be made of leather, cotton or a
35 hook and loop connection (Velcro® fastening).

The distal pad 3 may carry another strap or fastening means 9 to be
located around the big toe and preventing the pad from sliding off. This strap 9
suitably comprises a hook and loop connection for easy fastening and adjustment.

The brace according to the invention can be used in a dynamic way. Since

CLAIMS

1. A hallux valgus brace comprising a three point lever means for correcting the position of the big toe, wherein the brace including the three point lever means is designed to be located distally of the metatarsal joint, wherein the three points of the lever means are one point on the medial side of the first phalanx of the big toe, one point on the lateral side of the distal end of the big toe, and one point on the ball of the foot.
2. A brace according to claim 1, wherein the brace comprises a proximal pad pressing on the first phalanx of the big toe, a distal pad pressing on the distal end of the big toe, and a lever arm pressing on the ball of the foot.
3. A brace according to claim 2, wherein the distal pad is adapted to press on the distal end of the first phalanx of the big toe.
4. A brace according to claim 2 or 3, wherein the distal pad is disposed on an adjustable arm.
5. A brace according to claim 4, wherein the adjustable arm is secured to a sleeve which is slidable and may be fixed with glue.
6. A brace according to any one of the preceding claims, wherein the brace is manufactured from steel wire and steel pads.
7. A brace according to any one of claims 2-6, wherein the lever arm is provided with a silicone tube.
8. A brace according to any one of the preceding claims, wherein a strap is provided for fitting around the third toe.
9. A brace according to claim 7, wherein the strap is made of rubber or plastic or a hook and loop connection.
10. A brace according to any one of the preceding claims wherein the distal pad carries a strap to be located around the big toe.